REVIEW ARTICLE

Overview of Materiovigilance Programme of India

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ABSTRACT

The Medical devices vigilance also known as Materiovigilance, is the collection,assessment, reporting and identification of trends in incidents resulting from the uses of medical devices (ex. instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article etc.). To ensure the safety of medical devices in India, a Materiovigilance Programme of India (MvPI) has been implemented from government of India in 2013 and it was formally launched on July 6, 2015, with collaboration of Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) as the National Coordinating Center (NCC). The collected and generated safety data will support to Central Drug Standard Control Organisation (CDSCO) for giving recommendation for safe use of medical devices in Indian population.

Keywords: Central Drug Standard Control Organisation (CDSCO), Materiovigilance, Medical Device, Safety.

INTRODUCTION

Materiovigilance is the supervision of adverse events occurring due to use of medical devices in patients. It is helping to develop the healthcare system of India. The word materiovigilance is derived from two Greek words “materio"- which means materials and "vigilare" meaning to keep awake or alert, to keep watch.Materiovigilance, as defined by the World Health Organization (WHO), is the science and activities relating to the detection, assessment, understanding and prevention of adverse events caused by medical devices. The purpose of medical devices for the identification, treatment, diagnosis, and cure of illness that may sometimes initiate adverse reactions which needs to be monitored and prevented. So, thus a vigilance system is required to supervise the adverse events[1]. In the beginning, the marketed medical devices were regulated according to the Drugs and Cosmetics Act, 1940 and Rules 1945. After that in year 2017, an absolute rule was outlined to regulate the medical devices that existing in the Indian market called as Medical Device Rules, 2017[2].

Medical device includes any instrument, implant, machine, appliances, equipment, grafting material, reagent for in vitro use or other article used on itself or combinedly as well as software needed for it to function properly, which is proposed to be used on patients by manufactures for the following scopes[3]:

(a) For diagnostic, prevention, control, treating or lessening the diseases.

(b) For diagnostic, control, treating, for reducing or counteracting an injury, impairment, and disabilities.

(c) For learning, substituting, or altering component of the anatomy or a physiological process.

(d) For grand achievement in conception.

MATERIOVIGILANCE PROGRAMME OF INDIA

In current scenario, there are need to regulate the safety surveillance of medical devices in India for prevention of unexpected events due to uses of medical device. The Ministry of Health and Family Welfare (MOHFW) has authorized the MvPI, an organisation for monitoring the safety of medical equipment affiliated from the Government of India in year 2013. The MvPI was officially introduced on July 6, 2015 at Indian

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Pharmacopoeia Commission (IPC), Ghaziabad by the Drugs Controller general India (DCGI). All prescriber, nursing officers and patients/consumers be made able to report Medical Devices Associated Adverse Events (MDAEs) to SreeChitraTirunal Institute of medical Sciences & technology (SCTIMST), Thiruvananthapuram or National Coordination Centre (NCC) - IPC[4]. The reported, collected and generated safety data will support to make easier in giving recommendations to Central Drugs Standard Control Organisation (CDSCO) and on directing of safe use of medical devices in Indian Population. Due to increasing number of cases of malfunctioning in many medical equipments and numerous medical device related adverse events, developing to further complications in patients and in most severe cases life-threatening conditions, the significance and necessity of MvPI are rising from previously days. Soon after in year 2018 onward, the IPC functions as NCC for MvPI as well NCC for Pharmacovigilance Programme in India (PvPI). MvPI has Medical Device Adverse Events Monitoring Centres (MDMCs) all over the country. To make sure effective of Adverse Events reporting from all respective individuals centres, this programme had established several tools for Adverse Event reporting to create India specific data[5]. For implementation of MvPI effectiveness, it is recognized that the integration of biomedical engineering department (BMED) at the health facilities/institutions is fundamental for further harmonisation with other departments. Hence, for functions as MDMCs, the preferences have been given to the institutes with BMED.

Different Medical Device Adverse Events Monitoring Centres Across India:

In India, there are ten MDMCs which have been recognized under MvPI that work to report MDAEswhose counts has been expanded to 150. Since 2015, the adverse events reporting rate has also increased. Through MvPI, more than 7000 reports have been submitted to IPC, Ghaziabad. For appropriate identification, reporting and collection of any suspected or definite MDAEs, MDMCs are responsible. MDAEs are classified into five categories: not related, unlikely, possible, probable, and causal relationship, respectively. MDMCs will send the reported data to NCC-IPC every month for review and analysis. IPC, Ghaziabad is the individual custodian of MvPI database. NCC is responsible to coordinate with all MDMCs nationwide and connects all concerned issues to the CDSCO. Apart from this, they collaborate with global authorities. It also provides financial support to SCTIMST, the National Health Systems Resource Centre (NHSRC), and MDMCs. SCTIMST functions as the NCC and gives help in all technical matters. NHSRC works as a technical support partner in the MvPI. Ultimately, all concerns are transferred to the CDSCO, i.e., a national regulatory authority ensuring safety. CDSCO is responsible for taking decisions on recommendations by the NCC-MvPI. The organizational structure of MvPI is represented in Figure 1.

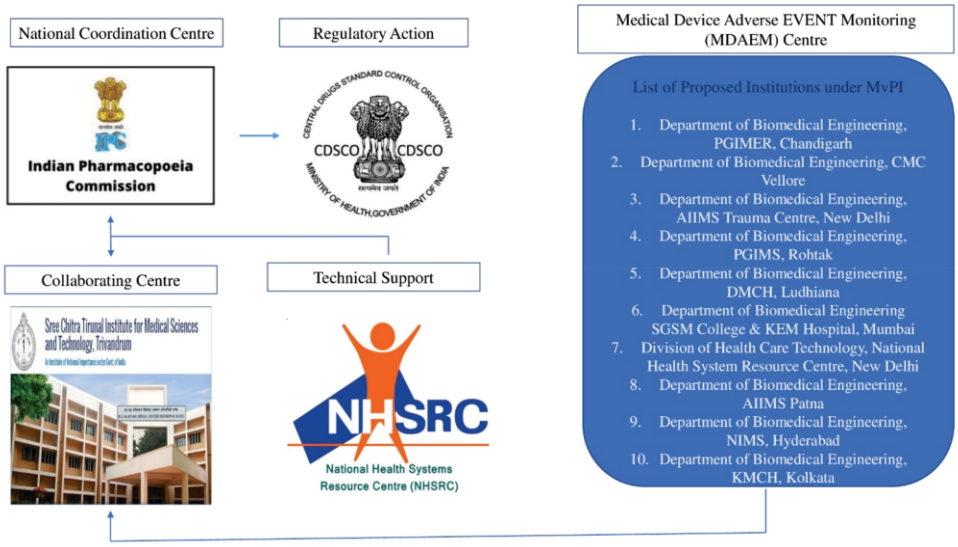

National Coordination Centre
Regulatory Action
Indian Pharmacopoeia Commission
CDSCO
Collaborating Centre
Technical Support
Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum
NHSRC
National Health Systems Resource Centre (NHSRC)
Medical Device Adverse EVENT Monitoring (MDAEM) Centre
List of Proposed Institutions under MvPI
1. Department of Biomedical Engineering, PGIMER, Chandigarh
2. Department of Biomedical Engineering, CMC Vellore
3. Department of Biomedical Engineering, AIIMS Trauma Centre, New Delhi
4. Department of Biomedical Engineering, PGIMS, Rohtak
5. Department of Biomedical Engineering, DMCH, Ludhiana
6. Department of Biomedical Engineering SGSM College & KEM Hospital, Mumbai
7. Division of Health Care Technology, National Health System Resource Centre, New Delhi
8. Department of Biomedical Engineering, AIIMS Patna
9. Department of Biomedical Engineering, NIMS, Hyderabad
10. Department of Biomedical Engineering, KMCH, Kolkata

Figure 1: Diagrammatic Representation of MDEM Under MvPI

OBJECTIVES OF MATERIOVIGILANCE PROGRAM OF INDIA

The MvPI was began with the objectives to make safe the healthcare system and make sure the safety of medical device users and others by decreasing the recurrences of adverse events and malfunctions of medical eqipments[6].

The objectives are:

(a) To generate a countrywide system for monitoring of patient safety

(b) To scrutinise the risk–benefit ratio of medical equipment uses

(c) To create evidence-based data on the safety of medical equipment

(d) To support CDSCO in making precise decision process on the use of medical equipment

(e) To convey the safety information on the use of medical equipment among stakeholders to diminish the risk

(f) To develop as a national coordination center of excellence for materiovigilance activities

(g) To work together with other healthcare organizations and international body for the exchange of data information and its management

Regulation of Medical Devices Under Drug and Cosmetic Act:

In our country, at present days only notified medical devices are regulated as Drugs under the Drugs and Cosmetics Act 1940 and Rules made there under in 1945 that are given as following[7] : (A) Substances used for in vitro diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant covered under sub-clause (i); (B)Substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified under subclause (ii); and (C) Devices notified from time to time under subclause (iv), of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940

POST MARKETING SURVEILLANCE APPROACHES IN WORLDWIDE

In 2011, a global organization with the designation of International Medical Device Regulators Forum (IMDF) was establishedwith the primary goal of accelerating the coordination of international medical devices regulation and to reinforce the foundation of Global Harmonization Task Forces (GHTF). Ten countries participated in IMDF management committee i.e., Australia, Brazil, Canada, China, European Union, Japan, Russia, Singapore, South Korea, and USA. All these countries have founded their individual surveillance systems for active and passive monitoring of MDAEs. The United State of America (USA) has founded a universal recognized system known as Food and Drug Administration (FDA) for the monitoring of food, medications, vaccines, and medical devices. In the same country, a mandatory and voluntary two schemes of medical device reporting have also been proposed[8], whereas United Kingdom (UK) has "Vigilance Reporting Scheme" as well the "Adverse Event Scheme" for the post-marketing surveillance of medical devices[9].The medical device manufacturers must take Vigilance Reporting Scheme and they should report adverse events within prescribed timeline. Although, it is voluntary for the healthcare professionals, hospital engineers and patients / consumers to take Adverse Event Scheme and report immediately. This scenario is different in Europe as all medical devices related issues are handed directly through National Competency Authority (NCA) from the manufacturer, while it is compulsory for general prescribers, doctors, and nurses to report the adverse event to manufacturer as well as NCA.The manufacturers are needed to submit a preliminary report of the serious medical device related adverse event within 2 calendar days. Later this, if the manufacturer realizes any relation between a medical device and life threatening or death or any health hazard, the appraisal is required to be reviewed within 10 days. Apart from this, very less serious or non-seriouscases can be reported within 30 calendar days[10]. In Japan country, medical devices are being regulated by the Pharmaceutical and Medical Device Agency that approaches come under certain rules and regulations which are required to be fulfilled for certification, quality assurance, and licensing including Japanese medical products[11]. In France, the medical device related adverse events are regulated by the “National Surveillance Commission" which is also known as the “Commission of Materiovigilance”. In Australia, the regulatory body, "Therapeutic Goods Administration” come under the Department of Health of the Australian Government that

regulates the medical device related adverse events[12]. Therapeutic Goods Administration keep data upto 5 years. In Canada, "Health Canada" Regulatory Authority regulates and ensure that all medical devices are safe and rationally used in both phases: pre- and post marketing surveillance and should be reported within 10 days after the manufacturer of a medical device becomes aware of an incident. In India, as already discussed that "Materiovigilance Programme of India" has been regulated the medical device related adverse events and reported to IPC within 15 calendar days of becoming aware of an eventand for non-serious events reporting to be done within 30 calendar days.

Pharmacovigilance Vs Materiovigilance

Materiovigilance is differ from Pharmacovigilance as given following:

	Pharmacovigilance	Materiovigilance
1.Definition	Pharmacovigilance is a system of monitoring Safety and Effectiveness of Drugs and other Pharmaceuticals.	Materiovigilance is a system of Monitoring Safety and Effectiveness of a Medical Device.
2. Programme Name in India	Pharmacovigilance Program of India	Materiovigilance Program of India
3. Launched Programme	In 2010	In 2015
4. Location of National Coordination Centre	Indian Pharmacopoeia Commission, Ghaziabad, previously in AIIMS, Delhi.	Indian Pharmacopoeia Commission Ghaziabad, SCTIMST and NHSRC.
5. Regulation	Finally, CDSCO will take necessary action against ADRs.	Finally, CDSCO will take necessary action against MDAEs.
6. Numbers of centres	At present, India have 395 adverse drug reaction monitoring centres in various medical colleges.	In India, currently medical device adverse events monitoring centresnumber has been increased to 150.

Reporting of Medical Device associated Adverse Events (MDAEs)

What to Report

All types of suspected Medical Device related Adverse Events (MDAEs) can be reported whether they are serious or non-serious, frequent, or rare regardless of an established causal relationship. A Medicaldevice can be any material, implant, incubator, instrument, apparatus, reagent, and any diagnostic tests, etc. Adverse Events description, Details of adverse event including description of device (deficiency or malfunction), clarification of threats associated with that device and the associated risk of patients with previous use can be provided in the MDAEs reporting form.

Who can Report

Practitioners, Biomedical Engineers, Clinical Engineers, Hospital Technology Managers, Pharmacists, Nurses, Technicians can report medical device adverse events.

Why to Report?

All associated medical device related adverse events should be reported in order to protect public health. Any unreported adverse events may lead to serious or death of patients.

Where to Report

The Healthcare workers (doctors, nurses, dentists, pharmacists), Manufactures and Patient/Consumers can report MDAEs to SCTIMST or NCC. Duly filled MDAEs Reporting Form can be send to SCTIMST or NCC- MvPI, Biomedical Technology Wing, Poojappura, Thiruvananthapuram, 695012, Kerala, India or Can directly email with scanned copy of the duly filled form to mvpi@sctimst.ac.in.

How to Report

MDAEs Medical Device Adverse Event Reporting Form [Figure 2] can be downloaded from the website of IPC (www.ipc.gov.in) to report adverse event associated with medical devices. MDAEs can also be reported via PvPI helpline number (1800 180 3024) on weekdays from 9:00 am to 5:30 pm.

MEDICAL DEVICE ADVERSE EVENT REPORTING FORM

Materiovigilance Programme of India

FOR MDMC/NCC USE ONLY

Type of report: Initial ☐ Follow-up ☐ | Report No. :

A. PATIENT DETAILS

1. Patient Hospital ID ----------
2. Sex: M ☐ F ☐
3. Age at time of Event or Date of Birth _____
4. Weight (Kg)_____

B. EVENT DETAILS

1. Event description-

Reason for the Event(Tick) a) Electrical ☐ b) Mechanical ☐ c) Electronic ☐ d) Biocompatibility ☐ e) Clinical application error ☐

2. Severity of the event (Yes ☐ No ☐) if yes please specify following

☐ Death (__/__/____) ☐ cause congenital-anomaly ☐ Life threatening ☐ Required intervention to prevent death or impairment of body function

☐ Hospitalization/Prolonged impairment/damage ☐ Disability ☐ Other (specify).....

3. Date of event -(dd/mm/yyyy)

4. Location of the event- OPD ☐ IPD ☐ Others (Please specify).....

5. Device category: (A) Therapeutic ☐ Diagnostics ☐ Both ☐ (B) Implantable device ☐ Non Implantable device ☐

(C). Single use device ☐ Reusable device ☐ Reuse of manufacture marked single use device ☐

6. Date-

Last preventive maintenance	Last calibration

7. Location of device after the incident:

Place of use ☐ Place of reporter ☐ Place of Manufacture/vendor ☐ With patient or end user ☐

8. Is device in use after incident Yes ☐ No ☐

9. (A) Is same model device available in organisation? Yes ☐ No ☐ If yes, Quantity.....

(B) Organization - Healthcare facility ☐ Manufacturer ☐

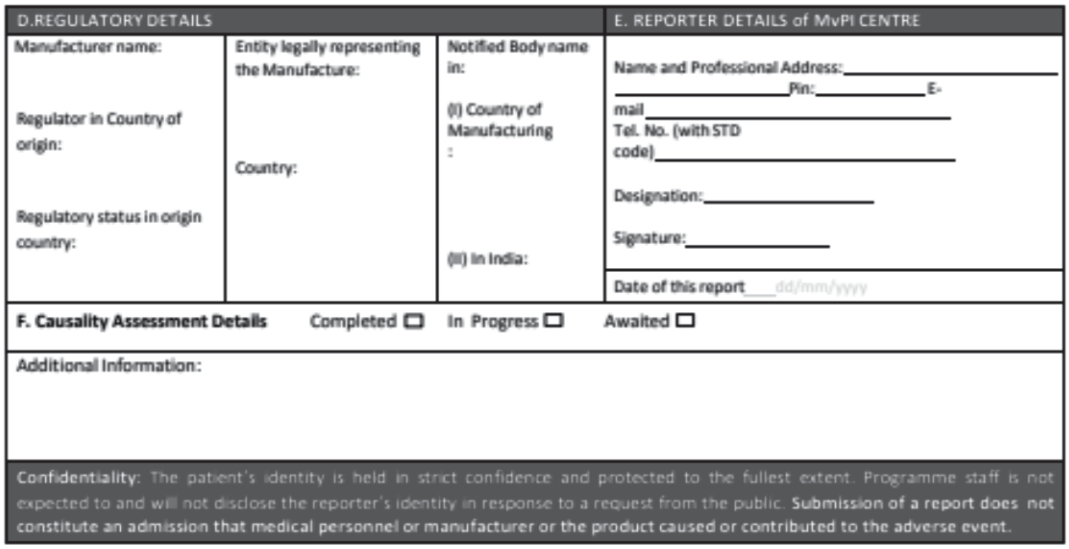
C. MEDICAL DEVICE(S) DETAIL

Name of Medical Device (1)	Manufacturer (2)	Brand Name (3)	Model No. (4)	Serial No. (5)	Batch No./ Lot No. (6)	Catalogue No. (for instruments only)	Date of installation/ implantation/ explantation (8)	List of Accessories (9)

10. Actions taken immediately after incident

11. A Whether other medical devices were being used at same time with above device for therapeutic of diagnostic service? If yes, please specify.....

11 B. Any history of adverse event(s) from device with same serial/model/catalogue number. If yes please specify.....



D.REGULATORY DETAILS			E. REPORTER DETAILS of MvPI CENTRE
Manufacturer name: Regulator in Country of origin: Regulatory status in origin country:	Entity legally representing the Manufacture: Country:	Notified Body name in: (ii) Country of Manufacturing : (iii) In India:	Name and Professional Address:_____ Pin:_____ E-mail _____ Tel. No. (with STD code)_____ Designation:_____ Signature:_____ Date of this report___ dd/mm/yyyy
F. Causality Assessment Details	Completed ☐	In Progress ☐	Awaited ☐
Additional Information:			

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the adverse event.

National Collaborating centre-Materiovigilance Programme of India.

Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) under the Department of Science & Technology, Government of India. Biomedical Technology Wing, Poojappura, Thrivananthapuram 695012,Kerala. Phone: 91- 471 – 2340411, Fax: 91- 471 -2341814, Email: head-bmtw@sctimst.ac.in.

National Coordination Centre-Materiovigilance Programme of India.

Indian Pharmacopoeia Commission (IPC), Ministry of Health and Family Welfare, Government of India, Sector-23,Rajnagar, Ghaziabad-20002, Tel.:0120-2783400, 2783401, and 2783392, FAX: 0120-2783311, Email. ipclab@vsnl.net, pvpi.ipcindia@gmail.com

Technical support and Resource Centre- Materiovigilance Programme of India.

National Health System Resource Centre (NHSRC), NIHFW campus Baba Gangnath marg, Munirka, New Delhi-110067, Phones: 011 26108982 / 83 / 84 / 92 /93, Fax: 011-26108994 Email: nhsrc.india@gmail.com.

Where to report

- **Duly filled Medical Device Adverse Event Reporting Form can be send to Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), National Collaboration Centre-Materiovigilance Programme of India), Biomedical Technology Wing, Poojappura, Thrivananthapuram 695012,Kerala,India.**
- **Or Can directly email the duly filled form to mvpi@sctimst.ac.in.**
- **Call on Helpline no. 1800 180 3024 to report Adverse event.**

Event description Details of adverse event including description of device (deficiency or malfunction), clarification of hazards associated with device and the associated risk of patient, user or person any possible risk to patient associated with previous use.

Additional Information Other relevant information related to treatment should be provided.

Figure 2: Medical Device Adverse Reporting Form

Example for Materiovigilance:

The manufacturer has issued a batch of blood glucose test strips. According to instructions the patients use the strips. Because of wrong readings, wrong insulin dosage was taken by the patient which leads to hypoglycaemic shock and hospitalization.

Another example is the patients facing problems related to malfunction of cardiac pacemaker that leads to output failure or failure to capture or pacemaker-medicated tachycardia or runaway pacemaker etc. Because of these problems patients can suffer syncope and cardiac arrest.

Future Prospects of Materiovigilance Programme of India

If the MvPI has to be successful, the contribution at root level has to be accelerated. So, there is need to provide awareness among health-care workers and the general public about MvPI has to be strengthened. For increasing the awareness, we should know what exactly to report, that is potential barriers in reporting MDAEs. If they reported to regulatory authorities timely, it will help to those diseased patients that will be affected due to deficiency and malfunctions of using medical devices. Academic curricula MBBS, Postgraduate programs, nursing, dental and paramedical courses should be updated to includeMvPI, and the knowledge of reporting MDAEs. The number of materiovigilance centres are increasing continuously for implementation of MvPI. MvPIhas key role in prevention of medical device associated health hazard.

CONCLUSION

In a few past years, the medical device's uses are found to be frequently by doctors across all over world including India. In spite of that, there are not satisfactory tool to safe guard the patients from the undesired events. Materiovigilance Programme of India is a good initiative to make sure the safety of medical device. This programme will be also significantly reducing the risk associated to the use of medical devices by avoiding the repetition of aversive effects. Therefore, it is the moral responsibility for all healthcare professionals to report MDMEs to IPC, Ghaziabad through submission of reporting form so that CDSCO can give recommendations to prevent medical device related health hazards.

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